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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,064	10/28/2003	Neal R. Cutler	CUTLER-07776	5953
7590 10/06/2004			EXAMINER	
Thomas W. Brown MELDEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 10/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/695,064

Applicant(s)

CUTLER, NEAL R.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### **Claims 1-8 are presented for examination.**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshlack et al. (U.S. Patent No. 6,261,599B1).

Oshlack et al. teach sustained release oral opioid analgesic dosage form comprising opioid analgesics such as tramadol, propoxyphene or mixtures thereof in a tablet form useful for providing analgesia in a patient. (abstract, column 3, lines 40-67, column 4, line 61, column 6, lines 23-26, column 7, lines 27-30, lines 55-60, column 25-26, claims particularly, 1, 4 and 5). Oshlack et al. teach that the tablet form above can be further coated with sustained-release coating. (column 11, lines 9-22). Oshlack et al. teach the formulation can be formulated with an immediate release therapeutically active agent for prompt therapeutic effect and the immediate release therapeutically active agent may be incorporated by coated on the surface of the compressed tablet. (column 11, lines 30-37).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable Oshlack et al. (U.S. Patent No. 6,261,599 B1) in view of Bartholomaeus (U.S. Patent No. 5,601,842).

Oshlack et al. teach sustained release oral opioid analgesic dosage form comprising opioid analgesics such as tramadol, propoxyphene or mixtures thereof in a tablet form useful for providing analgesia in a patient. (abstract, column 3, lines 40-67, column 4, line 61, column 6, lines 23-26, column 7, lines 27-30, lines 55-60, column 25-26, claims particularly, 1, 4 and 5). Oshlack et al. teach that the tablet form above can be further coated with sustained-release coating. (column 11, lines 9-22). Oshlack et al. teach the sustained release formulation provide analgesia in a patient for, e.g. 8-24 hours. (column 3, lines 63-65).

Oshlack et al. do not teach the patient (subject) has been previously treated with tramadol monotherapy set forth in claim 2.

Bartholomaeus disclose all drug formulation available on the market for tramadol are immediate release forms which require administration 3 to 4 times per day in order to achieve good therapeutic effectiveness in relieving chronic pain and it would be a

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desirable relief to the patients if the frequency of administration could be reduced to once or twice daily. (abstract, column 1, lines 9-24).

It would have been obvious to one of ordinary skill in the art to employ the composition taught by Oshlack et al. to a patient treated previously with tramadol monotherapy in immediate release formulation since it is desirable to reduce the frequency of administration of tramadol therapy in immediate release formulation to once or twice daily as taught by Bartholomaeus.

One would have been motivated to switch a patient previously treated with immediate tramadol therapy to sustained-release Oshlack et al. formulation to achieve up to 24 hours of pain relief with desirable once a day dosing in treatment of pain.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (U.S. Patent No. 6,261,599 B1) as applied to claims 1-6 above, and further in view of Straub et al. (U.S. Patent No. 6,395,300 B1).

Oshlack et al. as applied as before.

Oshlack et al. do not teach the sublingual dosage form set forth in claim 7 and an intranasal dosage form set forth in claim 8.

Straub et al. teach propoxyphene and tramadol can be administered intranasal or sublingually. (column 4, lines 27-30, column 7, line 25, column 13, lines 16-26).

It would have been obvious to one of ordinary skill in the art to formulate the composition comprising propoxyphene and tramadol taught by Oshlack et al. in intranasal or sublingual formulation since Straub et al. teach that each of the agents are

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well-known to be formulated in intranasal or sublingual formulation. One would have been motivated to formulate the composition comprising propoxyphene and tramadol taught by Oshlack et al. to provide various selection of formulation administrable by the each of the active agent to accommodate each of the patient's preference in route of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

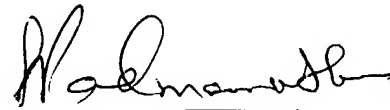
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
September 22, 2004